

EXHIBIT B

LAWRENCE GOLDKIND, MD.

**9010 MARSEILLE DRIVE
POTOMAC, MD 20854-3120
HOME: 301-765-9671
FAX: 301-765-0208**

Current position:

**Assistant Professor of Medicine
Department of Gastroenterology
Walter Reed National Military Medical Center Bethesda
Uniformed Services University of Health Sciences
School of Medicine
Bethesda, Maryland**

EDUCATION

1980 University of Maryland, M.D.
1976 University of Pennsylvania, B.A. International Affairs, Summa cum laude

POSTGRADUATE TRAINING

1986-1987 Senior Fellowship Training in Therapeutic Endoscopic Retrograde
Cholangiopancreatography
Meir Hospital, Israel

1984-1986 Fellowship in Gastroenterology
Boston University Hospital and Boston City Hospital

1983-1984 Research and Clinical Nutrition Fellowship
Harvard University/Massachusetts Institute of Technology

Original research project evaluated aspects of bioavailability of selenium when delivered via the enteral and parenteral routes. The study was conducted on inpatient volunteers at the Massachusetts Institute of Technology at the Clinical Research Center. I.R.B. approval and adherence to regulatory and safety protocols was required. Active participation in research conferences and authorship of back round section of five year multimillion dollar interventional study on dietary fat and breast cancer.

1980-1983 Intern, Junior Assistant Resident, Senior Assistant Resident,
1980-1984 Internal Medicine

University of Maryland Hospital

APPOINTMENTS

2003- present: Assistant professor of Medicine, Uniformed Services University of Health Sciences

1999-present Attending Staff, Division of Gastroenterology Walter Reed National Military Medical Center, Bethesda, Maryland

1983-1984 Nutrition Research Fellow
Harvard University School of Medicine

1984 Department of Nutrition, Clinical Research Fellow
Massachusetts Institute of Technology

1983-1984 Associate in Medicine
Boston University Medical Center

CERTIFICATION AND LICENSURE

1999-present Maryland Medical License

1986-present Florida Medical License

1987 Board Certified in Gastroenterology

1983 Board Certified in Internal Medicine

1983 Massachusetts Medical License

1981 Diplomat, National Board of Medical Examiners

WORK EXPERIENCE

1999-present: **Gastroenterology Staff Physician, Walter Reed National Military Medical Center, Bethesda, Maryland**

2003-present: **Assistant Professor of Medicine, Uniformed Services University of the Health Science, Bethesda Maryland**

2001-2003: Deputy Division Director, Division of Anti-inflammatory, Analgesic and Ophthalmic Drug Products, Center for Drug Evaluation and Research. Food and Drug Administration

1998-2000: Medical Officer, Division of Gastrointestinal and Coagulation Drug Products, Center for Drug Evaluation and Research, Food and Drug Administration

1987-1998 Gastroenterology private practice, Tampa, Florida

1994-1998 Chairman, Division of Gastroenterology
University Community Hospital
Tampa, Florida

1993-1998 Member, J.A.E.B Center for Health Research, Independent I.R.B.

HONORS AND AWARDS

1980 Dean's Fellowship

University of Maryland School of Medicine
1976 Phi Beta Kappa

PUBLICATIONS

1. Rogers, E.L., Goldkind, L., Goldkind, S.F. "Increasing Frequency of Esophageal Cancer Among Black Male Veterans." CANCER 49 (1982):610-617.
2. Rogers, E.L., Goldkind, S.F., Goldkind, L., et.al. "Adenocarcinoma of the Lower Esophagus." Journal of Clinical Gastroenterology 8 (1986):613-618.
3. Rofecoxib versus placebo ulcer rates. Editorial, Gastroenterology 2000;118:638-639
4. Brinker, A., Goldkind, L., Bonnel, R., Beitz, J. Spontaneous Reports of Hypertension Leading to Hospitalization in Association with Rofecoxib, Celecoxib, Nabumetone and Oxaprozin. Drug Aging 2004;21 (7): 479-484
5. Laine, L, Goldkind, L. Rastom, A NSAIDs and Hepatic Toxicity: A Systematic Review of Randomized Controlled Clinical Trials Clinical Gastroenterology and Hepatology , Clinical Gastroenterology and Hepatology 2005
6. Goldkind L, Laine L. A Systematic Review of NSAIDs Withdrawn From the Market Due to Hepatotoxicity: Lessons Learned From the Bromfenac Experience. Pharmacoepidemiology and Drug Safety, 2006
7. Goldkind L, Simon, L. Patients, their doctors, nonsteroidal anti-inflammatory drugs and the perception of risk. Arthritis Res Ther. 2006;8(2):105. Epub 2006 Mar 2.
8. Peura DA, Goldkind L, Balancing the gastrointestinal benefits and risks of nonselective NSAIDs. Arthritis Res Ther. 2005;7 Suppl 4:S7-13. Epub 2005 Sep 15.
9. How common is diclofenac-associated liver injury? Analysis of 17, 289 arthritis patients in a long-term prospective clinical trial. Laine, Loren¹; Goldkind, Lawrence²; Curtis, Sean P.³; Connors, Laurine³; Yanqiong Zhang³, Cannon, Christopher⁴ Clinical Gastroenterology and Hepatology 2008
10. Moore A, Cryor B, Goldkind L et al . Evidence for endoscopic ulcers as meaningful surrogate endpoint for clinically significant upper gastrointestinal harm. Clinical Gastroenterology and Hepatology ; 2009
11. Simon L, Strand V, Boers M, Brooks P, Tugwell P, Bombardier C, Fries J, Henry D, Goldkind L, Guyatt, Laupacis A, Lynd L, MacDonald T, Mamdani M,

Moore A, Saag K, Sillman A, Stevens R, Tyndall A., How to Ascertain Drug Safety in the Context of Benefit. Controversies and Concerns. J Rheumatol September 2009 36(9):2114-2121;

12. Moawad F, Goldkind L. An unusual cause of colonic ischemia. Southern Medical Journal 2009; 102 (4): 105-107
13. Armbruster S, Goldkind L, A 5-Year Retrospective Review of Experience With Clostridium difficile-Associated Diarrhea. Military Medicine, 177, 4:456, 2012
14. Cash, Brooks D., Goldkind L. et al. "Accuracy of computed tomographic colonography for colorectal cancer screening in asymptomatic individuals." *Gastroenterology*. Vol. 132. No. 4.

ABSTRACTS

- 1) Rogers, E.L., Iseri O., Bustin, M., Goldkind, S.F., Goldkind, L. "Adenocarcinoma of the Esophagogastric Junction: A Distinct Entity." American Association for the Study of Liver Disease, Gastroenterology Research Group, May, 1981.
- 2) Goldkind, L., Cave, D.R., Jaffin, B., et. al. "A New Factor in Enteric Hyperoxaluria: Oxalobacter Formigens." American College of Gastroenterology, October, 1985.
- 3) Laine, Loren; Goldkind, Lawrence; Curtis, Sean P.; Connors, Laurine; Yanqiong Zhang, Cannon, Christopher . How common is diclofenac-associated liver injury? Analysis of 17,289 arthritis patients in a long term prospective clinical trial. DDW 2007
- 4) Moawad FJ, Goldkind L. An Unusual Case of Colonic Ischemia. Am J Gastroenterol. 2008;103:S184Cirigliano V and Goldkind L. Chronic
- 5) Granulomatous Colitis Following Coffee Enema. Poster presentation at ACG National Meeting, San Diego, CA, October 2013. Cirigliano, Vito, and Lawrence Goldkind. "Chronic Granulomatous Colitis Following Coffee Enema." *American Journal of Gastroenterology*. Vol. 108. 75 2013.

PRESENTATIONS

Clinical trial design for outcome trials on cardiovascular risk
International Workshop on COX-2 sponsored by the International COX-2 Study Group 1/28/-2/30/05
Arlington Virginia

Pharmacovigilance

American College of Rheumatology, Innovative Therapies in Rheumatology

3/4/05

Washington DC

Causality Assessment in Drug Safety Assessment

Outcome Measures in Rheumatology

OMERACT

University of Ottawa, Ontario Canada

May 27, 2008

Case presentation: Amitiza: Anatomy of a first cycle approval

American Course on Drug Development and Regulatory Sciences (ACDRS5)

University of California San Francisco, School of Pharmacy

January 13, 2009 Washington DC

FDA and Health Canada Advisory Committee Meetings
Primary Presentation

1998: Review of Gastrointestinal safety studies of Celecoxib

1999: Review of Gastrointestinal safety studies of Rofecoxib

2000: Review of Studies for heartburn treatment and prevention: omeprazole for OTC

2001: Review of outcome studies CLASS and VIGOR for labeling changes related to

Cox-2 and NSAID safety

2001: Update of Advisory committee and guidance on large outcome studies

2002: Presentation and discussion of Analgesic Drug Development

2002: Presentation Safety of NSAID and COX-2 inhibitors: Health Canada

2003: Safety review of post-marketing studies leflunomide

2010: Regulatory history of NSAID GI safety claims

- FDA primary review experience with gastrointestinal drug products including therapy for inflammatory bowel disease, proton pump inhibitors, H2 receptor antagonists for the indications of nonulcer/functional dyspepsia, heartburn, peptic ulcer disease, ulcer prevention, analgesics (including NSAID, COX-2 specific inhibitors as well as non-NSAID analgesics)
- FDA supervisory review and regulatory decision making for all anti-

inflammatory and non-narcotic analgesic drug products.

Journal review board:

Journal of Rheumatology
Gastroenterology
Clinical Gastroenterology and Hepatology
Pharmacoepidemiology and Drug Safety
Arthritis and Rheumatology Research
Biomedical Central Gastroenterology

Lawrence Goldkind MD